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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,186	07/20/2001	Leonard A. Smith	A33626A 067252.0107	8442

21003 7590 12/02/2004

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,186	SMITH ET AL	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,43,45-51,53,55,56,82,85 and 86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,43,45-51,53,55,56,82,85 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 42-43,45-51,53,55-56,82,85-86 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a **specific reference** to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the **relationship** (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

While Application serial number 09/611,419 was amended on January 23, 2001 to claim priority to Application serial number 08/123,975, the specific reference and relationship between these two Applications was not defined in the first sentence of the Specification and therefore did not prefect the priority Applicant sought to claim.

Application serial number 09/611,419 was amended to refer to Application serial number 08/123, 975, but the first sentence of the specification of 09/611,419 has not been amended in such a way that the priority has been perfected. No specific reference to and relationship between the two Applications were not set forth in the Amendment of the

Specification of Application 09/611,419. Resolution of the outstanding issue is essential to Applicant's claim for priority.

Additionally in the instant Application, 09/910,186, the first sentence of the Specification has been amended to refer to various Applications to which it desires to claim priority, but a specific reference and relationship has not been set forth. The priority claimed has not been perfected in light of the requirement to obtain priority having not been met. Resolution of the outstanding issue is essential to Applicant's claim for priority.

Application, 09/910,186, claims priority to 08/123,975 but copendency between 09/910,186 and 08/123,975 was not maintained and therefore direct priority is not permitted.

Objections/Rejections Withdrawn

2. The Specification is not longer objected to for improper incorporation by reference to essential matter, in light of Applicants stating, "that the amendatory material consists of the same material incorporated by reference in the referencing application".
3. The Specification is no longer objected to for referring to Table 1, in light of the submission of documentation that Table 1 was originally filed with Applicant's Original Specification and providing a duplicate of Table 1 for insertion into the Specification.
4. Claims 46-47 rejected under 35 USC 112; second paragraph for not depending from claim 45 has been obviated through amendment of the claims to depend from claim 45.
5. Claim 48 rejected under 35 USC 112, second paragraph for reciting essential methods steps have been obviated through amending claim 48 to recite that the polypeptide is produced.
6. Claims 50-51 rejected under 35 USC 112, second paragraph for not providing antecedent basis for the recitation of the term "said organism" has been obviated through amendment of the claims to recite the term ---cell------.
7. Claim 53 rejected under 35 USC 112, second paragraph for not providing antecedent basis for the recitation of the term "recovered" has been obviated through amendment of the claims to recite the term ---isolated------.
8. Claims 42-47,48-51, 53, 55-56, 82, 85-86 rejected under 35 USC 112, second paragraph for clearly setting forth the claimed invention, has been obviated through reconsideration of Applicant's definitions for the claimed invention and Applicants traversal.

Rejections Maintained

1. The amendment filed March 7, 2003 remains objected to under 35 USC 132, because it introduces new matter into the disclosure because the priority claim to Application serial number 08/123,975 has not been perfected.
9. Claims 85-86 rejected under 35 USC 112, second paragraph for not providing antecedent basis for the recitation of the term "total cellular protein"; his rejection is maintained because

claim 82 only expresses the nucleic acid and not the polypeptide, and claims 85-86 are directed to total cellular protein and not total cellular nucleic acid concentration. The rejection is maintained for reasons of record.

10. Claims 42-43,45-47,55-56, 82,85-86 rejected under 35 U.S.C. 102(b) as being anticipated by Halpern et al (May 1993) in light of Applicants definitions of the claimed invention (see instant Specification "a nucleic acid sequence selected from (page 7, lines 7-8)"; "selecting at least a portion of the codons encoding HC from codons preferred from expression in a host organism (page 7, lines 29-31)"; "fragments of the botulinum neurotoxin protein expressed by recombinant organisms. Specifically peptides comprising protective epitopes from the receptor binding domain (see page 11, lines 23-24); "The vaccine comprises fragments of the A and B toxins (page 11, lines 31-32)"; to include peptide epitopes and not the complete amino acid sequence of SEQ Id NO 8, wherein the claims are directed to a nucleic acid that encodes at least one epitope.

2. Claims 48 and 51 rejected under 35 U.S.C. 102(a) as being anticipated by Smith et al. (different inventive entity, priority date for yeast: Pichia pastoris claims, is not 1993, reference of record) for reasons of record.

3. Claims 42-43,45-47, 48-49, 50,53, 55, 82 rejected under 35 U.S.C. 102(b) as being anticipated by Whelan, SM et al (Accession Number M81186, reference of record), for reasons of record.

Response to Arguments

4. Applicant's arguments filed August 25,2004 have been fully considered but they are not persuasive.

5. The amendment filed March 7, 2003 objected to under 35 USC 132, because it introduces new matter into the disclosure is traversed on the grounds that the instant Specification claims priority to 08/123, 975 and the disclosure of Thompson et al and Whelan et al were both incorporated by reference, concluding that no New Matter has been added to the Specification.

6. The examiner upon reconsideration found that the earliest priority claimed from Application serial number 08/123,975 has not been perfected as the earliest application was abandoned at the time of filing of the Specification of the instant Application. The specification remains objected to under 35 USC 132, as the Amendments of the specification introduce New Matter at least at page 12, lines 7-14; page 13, lines 1-6; page 38, lines 6-7. While this rejection has been partially obviated, the priority claim has still not been perfected (see narrative

above) and SEQ ID Nos 37, 39, 40 and 41 are NEW Matter as original descriptive support for these SEQ ID Nos has not been provided through Applicant's priority claim to Application serial number 08/123,975.

7. The rejection of claims 42-43,45-47,55-56, 82,85-86 rejected under 35 U.S.C. 102(b) as being anticipated by Halpern et al (May 1993) is traversed on the grounds that Halpern et al does not disclose SEQ ID NO 8.

11. It is the position of the examiner that based upon the definitions provided in the instant Specification, that the claimed invention includes peptide fragments of SEQ ID No 8, that include at least one epitope Halpern et al (May 1993) anticipates the instantly claimed invention. The scope of what is now claimed includes portions of SEQ Id NO 8 based upon the claim language recited and the definitions provided in the instant Specification. See instant Specification "a nucleic acid sequence selected from (page 7, lines 7-8)"; "selecting at least a portion of the codons encoding HC from codons preferred from expression in a host organism (page 7, lines 29-31)"; "fragments of the botulinum neurotoxin protein expressed by recombinant organisms. Specifically peptides comprising protective epitopes from the receptor binding domain(see page 11, lines 23-24); "The vaccine comprises fragments of the A and B toxins (page 11, lines 31-32)"; to include peptide epitopes and not the complete amino acid sequence of SEQ Id NO 8, wherein the claims are directed to a nucleic acid that encodes at least one epitope. The alignment provided is not commensurate in scope with the instantly claimed invention. The rejection could be obviated by amending the claims to no longer recite [at least one epitope] and just to recite " comprises... SEQ ID NO 8." The rejection is maintained for reasons of record.

8. The rejection of claims 48 and 51 rejected under 35 U.S.C. 102(a) as being anticipated by Smith et al. (different inventive entity, priority date for yeast: Pichia pastoris claims, is not 1993, reference of record) is traversed on the grounds that Smith et al does not disclose SEQ ID NO 8 and the priority of the instantly claimed invention is that of 1993.

12. It is the position of the examiner that Smith discloses the claimed invention of a nucleic acid that encodes a Clostridium botulinum type B- Hc capable of being expressed in a yeast, specifically Pichia pastoris, wherein the nucleic acid need only encode an amino acid portion/peptide/fragment of SEQ ID NO 8, that comprises at least on epitope. The scope of what is now claimed includes portions of SEQ Id NO 8 based upon the claim language recited and the definitions provided in the instant Specification. See instant Specification "a nucleic acid sequence selected from (page 7, lines 7-8)"; "selecting at least a portion of the codons encoding HC from codons preferred from expression in a host organism (page 7, lines 29-31)"; "fragments of the botulinum neurotoxin protein expressed by recombinant organisms. Specifically peptides comprising protective epitopes from the receptor binding domain(see page 11, lines 23-24); "The vaccine comprises fragments of the A and B toxins (page 11, lines 31-32)"; to include peptide epitopes and not the complete amino acid sequence of SEQ Id NO 8, wherein the claims are directed to a nucleic acid that encodes at least one epitope. The alignment provided is not commensurate in scope with the instantly claimed invention. The rejection could be obviated by amending the claims to no longer recite [at least one epitope] and just to recite " comprises... SEQ ID NO 8." The rejection is maintained for reasons of record.

9. The rejection of claims 42-43,45-47, 48-49, 50, 55, 82 under 35 U.S.C. 102(b) as being anticipated by Whelan, SM et al (Accession Number M81186,) is traversed that the claims have been amended to remove the phrase "about 70%" and that the alignments show that the sequence of Whelan and SEQ ID NO 8 are not identical.

13. It is the position of the examiner that the scope of what is now claimed includes portions of SEQ Id NO 8 based upon the claim language recited and the definitions provided in the instant Specification. See instant Specification "a nucleic acid sequence selected from (page 7, lines 7-8)"; "selecting at least a portion of the codons encoding HC from codons preferred from expression in a host organism (page 7, lines 29-31)"; "fragments of the botulinum neurotoxin protein expressed by recombinant organisms. Specifically peptides comprising protective epitopes from the receptor binding domain (see page 11, lines 23-24); "The vaccine comprises fragments of the A and B toxins (page 11, lines 31-32)"; to include peptide epitopes and not the complete amino acid sequence of SEQ Id NO 8, wherein the claims are directed to a nucleic acid that encodes at least one epitope. The alignment provided is not commensurate in scope with the instantly claimed invention. The rejection could be obviated by amending the claims to no longer recite [at least one epitope] and just to recite " comprises... SEQ ID NO 8." The rejection is maintained for reasons of record.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. US Pat. 5,919665 is cited to show a claim directed to a soluble fusion protein that comprises at least a portion of Clostridium botulinum fragment C linked to a poly-histadine tag (see claim 10).

17. US Pat. 6,270,777 is cited to show conserved metalloprotease epitopes (see all claims).

18. US Pat. 6,287,566 is cited to show protective peptides of C.botulinum A as vaccines.

19. US Pat. 6,461,617 is cited to show recombinant toxin fragment of Clostridium that lacks a portion of the Hc terminal of the heavy chain.

20. US Pat. 6521235 is cited to show an expression vector that comprises a nucleic acid sequence that encodes a polypeptide of Botulinum toxin C fragment and is an immunogen (see claim 77).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
November 17, 2004

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER